K132120

DEC 12 2013

Beijing WanTeFu Medical Apparatus Co., Ltd.
Niantou Industrial Park, Machikou, Changping District, Beijing, China
Tel: 8610-60750950 Fax: 8610-60750961

510(K) Summary

Date: 2013-12-11

1. Sponsor

Beijing WanTeFu Medical Apparatus Co., Ltd.
Niantou Industrial Park, Machikou,
Changping District, 102200, Beijing,China
Tel: 8610-60750950 Fax: 8610-60750961

2. Submission Correspondent

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3. Summary of technological characteristics of proposed Device:

PRODUCT	SPECIFICATIONS	REF
Safety Syringe	1 ml	110101
	2.5 ml	110251
	3 ml	110301
	5 ml	110501
	10 ml	111001
Retracting Needle	25G 1"	212551/222551
	23G 1"	212351
	22G 1"	212251
	21G 1 1/8"	212161
	30G 1"	223051/213051
	21G 1 1/4"	212171
	22G 1 1/4"	212271
Filling Needle (Optional)	18G 1"	311812

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- **Trade Name:** WTF Secura Safety Syringe (with Needle)
- **Common Name:** Safety syringe（with needle）
- **Classification Name**: Piston Syringe
- **Review Panel:** General Hospital
- **Product Code:** FMF, FMI, MEG
- **Regulation Number:** 880.5860
- **Device Class:** II
- **Predicate Device Trade name:** BD Integra 1ml Syringe K023752
- **Predicate Device manufacturer:** BD Medical Surgical 1 Becton Drive MC226 Franklin Lakes, NJ

4. Intended use:

The WTF Secura Syringe (with needle) is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin.
The WTF Secura Syringe (with needle) has a manually attached WTF Secura Retracting Needle. The WTF Secura Syringe (with needle) contains an inner mechanism used to allow the WTF Secura Retracting Needle to be retracted inside the plunger rod of the syringe when operator's thumb force released. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

5. Product Description:

a. **Description of each component:**

The WTF Secura Safety Syringe (with needle) is a sterile, single use, hypodermic syringe with a 6% Luer taper tip and an integrated Sharps Injury Prevention Feature. The syringe is provided in the following syringe sizes: 1ml, 2.5ml, 3m1, 5ml, and l0ml. and needle sizes: 21-30G. All sizes will be available with a Luer Lock tip and may be packaged as a syringe only, or syringe and needle combination. The syringe assembly consists of a lubricated polypropylene barrel with a graduated scale, a isoamyl stopper, a polypropylene plunger rod and a polypropylene sharps injury prevention feature. The sharps injury prevention feature consists of needle retracting performance before or after use, allowing for secure encapsulation of the needle point. The polypropylene syringe barrel incorporates a male 6% (Luer) connector, and is connectable to a compatible female 6% (Luer) connector. The

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needle assembly consists of indicidual lubricated retracting stainless steel needle and individual safety syringe.

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b. **Main material of WTF Secura Safety Syringe (with needle)** are Polypropylene pellets（PP）,Isoamyl rubber piston, retracting needle made of stainless tube，and its main package material are gumming paper and Medical composite membrane.

c. **Standards applied:** EN ISO 13485:2012/AC 2012, EN ISO 14971:2009, EN ISO 11135-1:2007, EN ISO 11607-1:2009, EN ISO 11607-2:2009, EN ISO 10993-1:2009, EN 556-1, EN1041:2008, EN 980:2008, ISO 9626, ISO 594-1,ISO 594-2, ISO 7886-4:2006, ISO 7886-1:1993, ISO 7864:1993, WTF/JS-H-AZS7-A-01-2010

Parts	Material of the part	Size	Standards	Component

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injection moulding	polypropylene	K4818 K4912	1. The requirements for polyethylene special material for medical use in YY/T0242-2007 shall be met. 2. The material meeting YY/T0242-2008 standard cannot be found due to procurement cause, and it shall be replaced by other similar materials. Furthermore, the biological performance of the used material shall be evaluated according to the requirements of GB/T 16886.1 (BS EN ISO 10993-1), so as to ensure that the requirements for safety of product material are met (the biological assessment and type inspection have been performed for the fabricated small batch of samples).	Sleeve, Outer core bar, Limit sheath, Inner core bar, Needle base connector cover, Needle base, Needle base connector, Protective cover, Protection cap, Luer adapters, Filling needle base
	TPE thermoplastic elastomer	A805-60 R62 E2000-4 5R92	Shore hardness: 65 Elongation rate: 270 Biological detection shall be performed for the first batch of supplied material (or entrust the third party to perform the biological detection). The haemolytic activity shall not exceed 5%; it shall have no acute systemic toxicity; in vitro cytotoxic response level shall be no larger than level 1, and there shall be no sensitization response.	Stop dog
	Color concentrate	Green, orange, blue, black	tinctorial strength 95-105%; Chromatic aberration≤0.3	The different colors correspond to different specifications needle base and needle base connector.

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Needle tube	Filling needle (bare needle)	0.4(27G),0.5(25G), 0.6(23G),0.7(22G),0.8(21G),0.9(20G)	Meet standards of ISO 8764 Sterile Hypodermic Needle for Single Use and ISO 9626 Stainless steel needle tubing for the manufacture of medical devices	Integrated needle、Filling needle、Filling needle tube
spring	Stainless tube	¢0.1，¢0.3	tensile strength≥110kg/mm	
O ring		Ø5.0×1.05 Ø3.9×1.05	silicon rubber Hardness 55~60	
silica gel or Isoprene rubber		2.5ml;3ml;5ml;10ml	1、Meet YY/T0243-2003 Plunger of sterile controllable safety syringe for single use （with detachable needle） 2、Meet WTF/JS-A-AZS3-2-06-2005	Plunger

6. Product Performance Test Summary

I. Product test report information

Property	Item	Conclusion
Biological property	Sterile	sterile growth
	Pyrogen	Non-pyrogen
	Hemolysis	Hemolysis ratio: 1% Compliance with technical requirements <5%
	Acute systemic toxicity	No acute systemic toxicity reaction
Chemical property	Readily oxidizable substance ml	0.1- Meet the requirement of potassium permanganate consumption <0.5
	pH value	0.04- Meet the requirement of pH difference <1.0
	Heavy metal μ g/ml	0.05- Meet the following requirement: namely total quantity of lead, zinc, tin and iron is ≦5, cadmium content is ≦0.1

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	Residual quantity of ethylene oxide μ g/g		Not detected- Meet the requirement that residual quantity of ethylene oxide is equal to or less than 10
Physical property	Controllable core pin		Qualified
	Self-destruction performance		Qualified
	Body adaptation		Qualified
	Volume tolerance		Qualified
	Piercing force of sword		Qualified
	Needle	Rigidity	Qualified
		Toughness	Qualified
		Corrosion resistance	Qualified
		Surface	Qualified
		Cleanliness inside the tube	Qualified
	Appearance		Qualified
	Scale length		Qualified
	Scale volume line		Qualified
	Zero line position		Qualified
	Metering number		Qualified
	Scale printing		Qualified
	Jacket length		Qualified
	Jacket hemming		Qualified
	Handle interval		Qualified
	Piston		Qualified
	Sliding property		Qualified
	Residual capacity		Qualified
	retracting needle	Appearance	Qualified
		Dimension	Qualified
		Upright connection	Qualified
		Smooth pinhole	Qualified
	Cone cover	Color	Qualified
		Separating force of sheath	Qualified
	Single packing mark		Qualified

III. Conclusion

Based on the test report analysis, main indexes of products meet the product standard requirements.

7 The Simulated Clinical Study Summary

According to the chapter 10 of "Guidance for Industry and FDA Staff-- Medical Devices with Sharps Injury Prevention Features on Aug.9, 2005". The WTF Secura Safety Syringe (with needle) had been evaluated by simulated clinical study. For this simulated test, there was only one failure among 1000 devices tested. This result is acceptable for confidence and statistical theory.

Generally, the WTF Secura Safety Syringe (with needle) which is designed and manufactured by Beijing WanTeFu Medical Apparatus Co., Ltd is easily to be handled and safe for clinical uses.

8. Indications for use:

The WTF Secura Syringe (with needle) is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin.

The WTF Secura Syringe (with needle) has a manually attached WTF Secura Retracting Needle. The WTF Secura Syringe (with needle) contains an inner mechanism used to allow the WTF Secura Retracting Needle to be retracted inside the plunger rod of the syringe when operator's thumb force released. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

9. Substantial Equivalence Discussion Summary:

The WTF Secura Syringe (with needle) was compared to the predicate devices (BD Integra Syringe) using the followingcriteria: syringe type, intended use(s), principle of operation, specific drug use, Length, Diameter, tip type, Volume, needle length, needle gauge, needle tip configuration, nozzle type, barrel marking specs, gradations legibility, needle cover dimensions, needle cover color, lubricant composition, lubricant amount/cm2, barrel transparency, delivery accuracy, reuse durability, needle cover strength, hub/needle bond strength, Biocompatibility, Materials, Labeling, Re-use prevention feature, Performance after shipping. The testing to applied standards provides additional evidence that the WTF Secura

Syringe (with needle) is substantially equivalent to the predicate devices in terms of safety, efficacy and performance.

The WTF Secura Syringe (with needle) performed in a similar manner to the predicate devices(BD Integra Syringe). The WTF Secura Syringe (with needle) performed equivalently to the BD Integra Syringe with respect to the following characteristics:
Overall performance:

- Ease of maintaining standard injection technique
- Ability to maintain aseptic technique
- Ability to aspirate medication from a vial
- Ability to read the syringe scale on the barrel
- Ability to passively re-shield and transport
- Ability to easily and safely dispose of the used device in a sharps container
- Perceived safety of the device

The differences between the WTF Secura Syringe (with needle) and the predicate devices do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 12, 2013

Beijing WanTeFu Medical Apparatus Company, Limited
Mr. Raymond Sun
Niantou Industrial Park, Machikou
Changping District
Beijing, China 102200

Re: K132120
Trade/Device Name: WTF Secura Safety Syringe (with Needle)
Regulation Number: 21 CFR 880.5860
Regulation Name: Safety Syringe (with Needle)
Regulatory Class: II
Product Code: FMF, FMI & MEG
Dated: September 5, 2013
Received: September 16, 2013

Dear Mr. Sun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132120

Device Name
WTF Secura Safety Syringe (with needle)

Indications for Use *(Describe)*
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2013.12.12 10:02:46 -05'00'